

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MERIAL LIMITED and MERIAL SAS,

Plaintiff,

v.

INTERVET INC.,

Defendant.

CIVIL ACTION

NO. 1:05-CV-3168-CAP

O R D E R

This matter is before the court on Intervet's motion to dismiss or, in the alternative, to transfer [Doc. No. 16].

Factual Background and Procedural History

This is a patent infringement action dealing with allegedly competing vaccines used to combat Post-Weaning Multisystemic Wasting Syndrome.

A. Post-Weaning Multisystemic Wasting Syndrome and Porcine Circovirus

Post-Weaning Multisystemic Wasting Syndrome ("PMWS") is a slow, progressive disease in young pigs that is characterized by difficulty breathing, weight loss, and death. PMWS affects roughly 5% of U.S. herds. Mortality in acutely affected herds varies from 5% to 50%, and chronically infected herds may sustain average losses of 15% from weaning to slaughter.

PMWS was first recognized in 1996 in Canada. Since then, hundreds of swine farms in Canada and Europe have been affected. The disease has also spread to swine farms in the United States.

While PMWS is the clinical disease, one co-factor responsible for causing PMWS is the porcine circovirus ("PCV").¹ There are two known "serotypes" of PCV called Type 1 and Type 2. Type 1 does not cause a known disease. Type 2 strains, however, can be found in the lesions of PMWS-affected pigs.

Scientists and veterinarians believe that piglets are most susceptible to PCV and subsequent PMWS after they have been weaned from their mothers when they are about 3-10 weeks old, hence the name "Post-Weaning Multisystemic Syndrome." Protecting piglets from PCV and subsequent PMWS can be done in two ways: by vaccinating a sow (an adult female pig) just before or during pregnancy, and thereby inducing a transfer of maternally derived antibodies to the piglets, or by vaccinating the piglets themselves.

Both Merial and Intervet have developed vaccines to combat PCV Type 2 ("PCV-2") and subsequent PMWS. These vaccines are the subject of this patent infringement suit.

¹ PCV received its name because its DNA is in the form of a ring.

B. Merial's CIRCOVAC Vaccine

Plaintiff Merial Limited ("Merial") develops, produces, and sells veterinary pharmaceuticals and vaccines for livestock, pets, and wildlife. Merial SAS is a wholly-owned subsidiary of Merial.

On April 9, 2002, the United States Patent and Trademark Office issued U.S. Patent No. 6,368,601 entitled "Porcine Circovirus Vaccine and Diagnostics Reagents" (the "'601 Patent"). The '601 Patent relates to strains of the PCV-2 virus. The '601 Patent is assigned to Merial SAS, the Queen's University of Belfast ("Belfast"), and the University of Saskatchewan ("Saskatchewan").

On February 6, 1998, Belfast, Saskatchewan, and Merial SAS entered into an agreement concerning PCV research that leads to patents (the "Tripartite Agreement"). In particular, the Tripartite Agreement granted Merial an "exclusive and worldwide right and license for industrial and commercial exploitation" of any patents obtained as a result of work done in connection with the Tripartite Agreement. Merial SAS was also given the right to grant sublicenses covering the patents to its affiliates.

In exchange for this grant, as well as royalties on the net sales of products manufactured under the covered patents, Belfast and Saskatchewan were granted the right to dispose of the patents to carry on any internal scientific, research, or teaching works. The Tripartite Agreement specifically prohibits Belfast and

Saskatchewan from exploiting the patents commercially or industrially or granting any right or license to any third party. The '601 Patent was obtained as a result of work done in connection with the Tripartite Agreement and is, therefore, covered by the Tripartite Agreement.

On April 14, 2006, Merial SAS, Merial's wholly-owned subsidiary, granted Merial the exclusive right to conduct "any and all activities world-wide relating to the filing, prosecution, and enforcement of" the '601 Patent in the United States. Merial claims that this written license agreement merely memorialized Merial SAS and Merial's prior oral agreement.

Merial SAS manufactures a PCV vaccine derived from the '601 Patent called CIRCOVAC. CIRCOVAC is designed to be used in pregnant sows. It works by producing high concentrations of Maternally-Developed Antibodies ("MDA") that can be passed to the piglets through the colostrum in order to provide them protection from the PCV-2 virus. Because the sow passes the MDAs to her piglets, Merial's CIRCOVAC provides passive immunization to the piglets.

CIRCOVAC is approved for use in Europe and Canada.² Although Merial is seeking authorization to market CIRCOVAC in the United

² CIRCOVAC was introduced into the Canadian market on March 20, 2006.

States, the United States Department of Agriculture ("USDA") has not yet granted Merial authorization to do so.

C. Intervet's PCV Vaccine

Similar to Merial, defendant Intervet researches, develops, and manufactures animal health products, such as veterinary vaccines and pharmaceuticals. Intervet currently offers four different swine pharmaceutical products and 23 different types of swine vaccines in the United States.

On February 13, 2003, Intervet gave notice to the USDA that it was developing a vaccine product to help halt the spread of PMWS associated with PCV infection. Approximately two and a half years later, on October 13, 2005, the USDA granted Intervet a conditional veterinary biological product license for the manufacture and distribution of its circovirus vaccine entitled "Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector" ("Intervet PCV vaccine"). The USDA issued the conditional license because it found there was a "need for the product to aid in the protection of disease caused by Porcine Circovirus." According to the conditional license, Intervet's PCV vaccine is manufactured in Delaware.

Intervet's PCV vaccine is labeled for use in pigs three weeks of age or older, the point at which the piglet's passive immunity has declined and the piglet can respond to the vaccine and develop

its own active immunity. Unlike Merial's CIRCOVAC vaccine, Intervet's PCV vaccine provides active immunization to the piglets in that, it is designed to stimulate a piglet's immune system to develop protection from the PCV-2 virus.³

Absent USDA approval of Merial's CIRCOVAC vaccine, Intervet's PCV vaccine is the only PCV-2 vaccine available to U.S. swine producers.

D. This Lawsuit

On December 12, 2005, Merial instituted this patent infringement action against Intervet claiming that Intervet has infringed, contributed to the infringement of, and/or actively induced the infringement of at least one of claims 9, 16, 32, 33, and 35 of the '601 Patent by making, using, selling, and/or offering to sell its PCV vaccine. Although no affidavit of service is present in the record, Intervet claims that it was served on March 10, 2006.

On March 31, 2006, before Intervet answered Merial's complaint, Merial filed a motion for a preliminary injunction [Doc. No. 13]. At the time that Merial filed its motion for a preliminary injunction, Merial was aware of the fact that Intervet

³ Because Intervet's vaccine is designed to be used on piglets who are three weeks of age or older, by definition, it provides no protection for piglets who are less than three weeks old or who have not been weaned.

was taking orders for its PCV vaccine in Canada and that Intervet had obtained a conditional license to sell its PCV vaccine in the United States. Merial claims it did not know Intervet was selling its PCV vaccine in the United States.

Approximately two weeks later, on April 10, 2006, Merial filed a motion for a temporary restraining order against Intervet [Doc. No. 14]. Merial claims that the motion for a temporary restraining order was necessitated by the fact that Intervet had begun selling its PCV vaccine in the United States.

One day later, Intervet filed suit in the District Court for the District of Columbia against Merial, Merial SAS, Belfast, and Saskatchewan seeking a declaratory judgment of non-infringement and invalidity of the '601 Patent. On the same day that Intervet filed its declaratory judgment action, Intervet also filed the present motion to dismiss or, in the alternative, to transfer this case to the District Court for the District of Columbia.

Six days after Intervet filed its motion to dismiss, on April 17, 2006, Merial amended its complaint to add Merial SAS as a plaintiff.

Legal Analysis

In its motion to dismiss, Intervet argues that the court should dismiss the action because Merial did not have standing to sue for patent infringement at the time that it filed suit and has

failed to join necessary parties. In the alternative Intervet asks the court to transfer the case to the District Court for the District of Columbia, where Intervet filed a patent infringement action against Merial and all three owners of the '601 Patent.

Standing to sue is a threshold requirement in any federal lawsuit. Sicom Systems Ltd. v. Agilent Technologies, Inc., 427 F.3d 971, 975 (Fed. Cir. 2005). Standing must be present at the time the suit is brought. Id. at 976. The party bringing the action bears the burden of establishing that it has standing. Id.

The requirement of standing is both a constitutional limitation on federal court jurisdiction and a prudential limitation on its exercise. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 112 S. Ct. 2130, 2136 (1992). The constitutional requirements for standing emanate from Article III of the United States Constitution, which states that federal courts may only adjudicate cases or controversies. Allen v. Wright, 468 U.S. 737, 750-51, 104 S. Ct. 3315, 3324 (1984). Constitutional standing requires only that the plaintiff have suffered an injury in fact, that there be a causal connection between the injury and the defendant's conduct, and that the injury be redressable by a favorable court decision. Lujan, 504 U.S. at 560, 112 S. Ct. at 2136.

In addition to constitutional standing, standing to sue for patent infringement is also controlled by the Patent Act, which provides that a "patentee shall have remedy by civil action for infringement of his patent." Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1376-77 (Fed. Cir. 2000) (citing 35 U.S.C. § 281 (1994)). Thus, standing to sue for infringement of a patent generally rests with the patent owner(s) or the owner's assignees and not a bare licensee. Sicom Systems, 427 F.2d at 976; Waterman v. Mackenzie, 138 U.S. 252, 255 (1891).

"While a licensee normally does not have standing to sue without joinder of the patentee, an exclusive license may be tantamount to an assignment for purposes of creating standing if it conveys to the licensee all substantial rights to the patent at issue." Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336, 1340 (Fed. Cir. 2006). Whether a transfer is an assignment or a license does not depend upon the name by which it calls itself but upon the legal effect of its provisions.

To determine whether an agreement to transfer rights to a patent amounts to an assignment, the court must ascertain the intention of the parties and examine the substance of the rights granted in the agreement. Id. At its heart, the question is, "Who owns the patent? Does the transfer or retention of certain rights amount to an assignment of the patent or not? A key factor has

often been where the right to sue for infringement lies." Aspex Eyewear, 434 F.3d at 1342.

Merial first argues that its relationship and agreements with Merial SAS conferred upon it the right to bring suit against Intervet. In particular, Merial argues that it had standing to bring suit because Merial SAS is a wholly-owned subsidiary of Merial. Merial also contends that its verbal agreement and nunc pro tunc written license from Merial SAS conferred standing upon Merial to sue in its own name without joining Merial SAS or the other two patent owners.

Neither Merial's relationship nor its agreements with Merial SAS conferred standing upon Merial to sue for patent infringement in its own name on December 15, 2005. As an initial matter, standing under the Patent Act cannot be based on the mere fact that Merial SAS is a wholly-owned subsidiary of Merial. Merial's ownership of Merial SAS alone does not make Merial the owner of the '601 Patent. See, e.g., DePuy, Inc. v. Dimmer Holdings, Inc., 384 F. Supp.2d 1237, 1239 (N.D. Ill. 2005) (dismissing case because the corporate parent of a patent owner lacked standing to sue for infringement); Beam Laser Systems, Inc. v. Cox Communications, Inc., 117 F. Supp.2d 515, (E.D. Va. 2000) ("ownership of corporate stock does not create equitable title in that corporation's property."); Lans v. Gateway 2000, Inc., 84 F. Supp.2d 112, 123

(D.D.C. 1999) (holding that the plaintiff did not have standing to bring a patent infringement action in his own name where he had assigned his rights in the patent to a company, even though he was the managing director and sole shareholder of that company); Site Microsurgical Systems, Inc. v. Cooper Co., Inc., 797 F. Supp. 333, 338 (D. Del. 1992) ("The Court is not convinced, and the plaintiff offers no authority, that a parent corporation effectively has the patent rights of owners, assignees, and licensees by virtue of its ownership of a subsidiary holding the patent."). Merial's ownership of Merial SAS, therefore, was not enough to confer standing upon Merial.

Merial and Merial SAS's verbal agreement also is not sufficient to confer standing upon Merial. To have standing to sue in its own name for patent infringement, Merial's license must be considered a virtual assignment. See Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1093 (Fed. Cir. 1998). While a license may be oral, if the license is going to be considered a virtual assignment, it must be in writing. Id. Accordingly, the alleged verbal agreement between Merial and Merial SAS did not confer standing upon Merial.

Perhaps in recognition of this flaw, Merial and Merial SAS entered into a written license agreement memorializing their alleged oral agreement on April 14, 2006 ("Merial License"). The

Merial License is retroactive, effective as of December 19, 2001, thus predating the filing of this suit. Nunc pro tunc assignments, like the Merial License, however, are not sufficient to confer retroactive standing upon Merial. Enzo APA, 134 F.3d at 1093 ("As a general matter, parties should possess rights before seeking to have them vindicated in court. Allowing a subsequent assignment to automatically cure a standing defect would unjustifiably expand the number of people who are statutorily authorized to sue."). Merial, therefore, did not have standing to sue Intervet on December 15, 2005.

To avoid dismissal and out of an "abundance of caution," Merial amended its complaint on April 17, 2006, to add Merial SAS as a party-plaintiff. Merial argues that the amendment relates back to the complaint. Thus, even if the court were to decide that Merial lacked standing at the time this action was filed, Merial argues that it cured the defect when it added Merial SAS because Merial SAS had standing based on the Tripartite Agreement and the amendment adding Merial SAS relates back to the time the suit was filed.

Even assuming Merial had constitutional standing such that it could amend the complaint to add Merial SAS,⁴ the amendment does

⁴ If Merial lacked Article III standing at the time the suit was filed, the defect could not be cured by the addition of a party

not satisfy the Patent Act's requirements for standing because the Tripartite Agreement did not confer substantial rights in the '601 Patent upon Merial SAS.⁵ First and most importantly, the Tripartite Agreement does not state that Merial SAS has the exclusive right to sue for infringement. See Sicom Systems, 947 F.3d at 979 (stating that the exclusive right to sue for patent infringement is an important and often dispositive right). Although the Tripartite Agreement requires Merial SAS to bear the relevant costs of an infringement action, this requirement is not tantamount to an exclusive right to sue for infringement. At most, it suggests that Merial SAS must participate in an infringement

with standing. See Schreiber Foods, Inc. v. Beatrice Cheese, Inc., 402 F.3d 1198 (Fed. Cir. 2005) ("In the area of patent infringement, this court has held that if the original plaintiff lacked Article III standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by the addition of a party with standing."); Wright v. Dougherty County, Georgia, 358 F.3d 1352, 1356 (11th Cir. 2004) (affirming dismissal of the complaint and stating that "[b]y lacking standing to bring a claim the appellants also lack standing to amend the complaint to consolidate with a party who may have standing"); Lans, 84 F. Supp.2d at 115 (D.D.C. 1999) ("The Court adopts the rule that a patent plaintiff may not amend the complaint to substitute a new plaintiff in order to cure a lack of jurisdiction, because a plaintiff may not create jurisdiction by amendment where none exists."). Because the Tripartite Agreement did not confer substantial rights on Merial SAS, the court does not reach this issue.

⁵ In addition, it appears to the court that one of the inventors, Mr. McNeilly, did not formally assign his rights to Merial SAS, Belfast, or Saskatchewan, until after this suit was filed.

action through the payment of costs.⁶ In fact, the Tripartite Agreement appears to contemplate cooperation between all three patent owners. For example, Paragraph 7.4 states that each of the owners must notify the other owners of any apparent infringement. It also states that Belfast, Saskatchewan, and Merial SAS shall closely cooperate in any procedure and/or defense. See id. (dismissing the complaint for lack of standing, in part, because Sicom was required to consult with the patent owner and the patent owner's consent was required before settling litigation).

Second, the Tripartite Agreement does not give Merial SAS unfettered discretion to assign its rights in the '601 Patent or grant sublicenses. The Agreement, for instance, only states that Merial SAS may grant manufacturing sublicenses to its affiliates. Merial SAS's ability to assign its rights is further limited by Paragraph 8, which states that subject to Merial SAS's limited right to grant sublicenses, the rights set out in the Tripartite Agreement cannot be assigned to a third party without the express agreement of all three owners. See Sicom Systems, 947 F.3d at 979 (holding that Sicom lacked standing, in part because the license

⁶ Similarly, although Paragraph 6.2 of the Tripartite Agreement requires Merial SAS to file and keep the patents in force, Belfast and Saskatchewan retained the right to file and maintain the patents in their own name at their own expense if they do not agree with the manner in which Merial SAS was filing or keeping the patents in force.

agreement limited Sicom's right to assign its interests in the patent).

Third, the Tripartite Agreement does not grant Merial SAS the sole right to use or make the '601 Patent. Paragraph 6.1 of the Tripartite Agreement specifically states that "[t]he ownership of all and any results, inventions, and technologies . . . shall be the common equally shared property of the Parties hereto." Further, as noted above, Belfast and Saskatchewan retained the right to freely dispose of the '601 Patent to carry on any internal scientific, research, or teaching works. At most, Merial SAS received the right to use, sell, and make the '601 Patent in the industrial and commercial fields.

Although the court recognizes that Belfast and Saskatchewan have submitted affidavits stating that Merial and Merial SAS have had the exclusive right to enforce the '601 Patent since before December 15, 2005, the court must first look to the plain language of the Tripartite Agreement. The plain language of the Agreement is unambiguous, and it does not grant Merial or Merial SAS the exclusive right to enforce the '601 Patent. Furthermore, the fact that Belfast and Saskatchewan have agreed nunc pro tunc to be bound by the decision in this case does not mean that they should not be joined as party-plaintiffs. See Prima Tek II, 222 F.3d at 1381 (holding that the patentee was a necessary party to the

infringement suit, even though the patentee had expressly agreed to be bound by any judgment rendered in an action to which its licensee was a party).

Accordingly, because Belfast and Saskatchewan retained substantial rights in the '601 Patent, Merial SAS did not have standing to sue solely in its own name for infringement. See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1468 (Fed. Cir. 1998) ("An action for infringement must join as plaintiffs all co-owners."). Intervet's motion to dismiss, therefore, is due to be granted.

Conclusion

For the reasons discussed above, the court GRANTS IN PART and DENIES IN PART Intervet's motion to dismiss [Doc. No. 16]. Intervet's motion [Doc. No. 16] is DENIED to the extent it seeks transfer of this case to the District Court for the District of Columbia and to the extent that it seeks dismissal with prejudice. Intervet's motion [Doc. No. 16] is GRANTED, however, to the extent that it seeks dismissal of this action without prejudice. This case is DISMISSED WITHOUT PREJUDICE and the clerk is DIRECTED to close the file.

Because the court concludes that Merial lacked standing to bring this lawsuit and, thus, dismissal is proper, Merial's motion for a temporary restraining order [Doc. No. 14] and Merial's motion

for a preliminary injunction [Doc. No. 13] are also DISMISSED as moot.

SO ORDERED, this 27th day of April, 2006.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge